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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/207,161	12/07/98	HILLMAN J	PF-0208US

HM12/0925

LEGAL DEPARTMENT
INCYTE PHARMACEUTICALS INC
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EXAMINER	
CARLSON,K	
ART UNIT	**PAPER NUMBER**
1653	15

DATE MAILED: 09/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/207,161	HILLMAN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *18 August 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 11-20* is/are pending in the application.

4a) Of the above claim(s) *12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

This Office Action is in response to Paper #14, filed August 18, 2000.

Claims 2-10 have been canceled. Claims 12-20 have been withdrawn from further consideration because these Claims are directed to non-elected Inventions. Claims 1 and 11 are currently under examination.

Maintenance of Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 11 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. The specification states that the IMP-2 protein is presumed to be a type II integral membrane protein and provides a method to confirm this presumption (page 50, line 6). The type II integral membrane proteins are stated to have an amino terminal cytoplasmic domain that is typically small and generally lacks enzymatic activity and are not directly involved in transmembrane signaling. The carboxy terminal extracellular domain typically comprises the active portion of the protein such as enzymatic or receptor binding domain activity (para. bridging pages 1-2). At page 2, para. 1, the specification compares IMP-2 to the mouse multigene E24 failing of type II integral membrane proteins and discusses expression patterns of mouse *Itm2* gene. At page 14, paras 104, the specification teaches the biochemical characteristics of IMP-2. In no place does the specification teach the function of IMP-2 protein. The IMP-2 protein sequence is deduced from the cDNA sequence and the protein itself has not been produced.

The specification teaches that IMP-2 can be used to treat liver diseases including liver tumors (page 4, line 29) and to treat a variety of tumors (page 5, line 3). IMP-2 is also taught to be useful for the diagnosis, prevention, or treatment of diseases associated with abnormal liver tissue including tumors. At page 28, para. 1 the specification teaches that IMP-2 or fragments or

derivatives thereof may be administered to a subject to treat disorders associated with abnormal liver functions as well as a variety of tumors. Conditions and diseases to be treated include liver tumors, primary biliary cirrhosis, lung, brain, prostate, breast, and bladder tumors.

The asserted utilities set forth in the specification are considered to be general utilities that would be applicable to the broad class of the invention. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Because Applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed.

Claims 1 and 11 are also again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments:

Applicants arguments begin at page 6. Applicants discuss the expression pattern of the claimed polypeptide and state that this expression pattern provides numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease. Applicants do not discuss what toxicology testing that the expression pattern will aid in determining, what drug will be developed by knowing this expression pattern or what disease will be diagnosed by knowing this expression pattern. Therefore, this argument is not persuasive.

Applicants discuss case law at page 7 and conclude that the rejection fails to demonstrate either that the Applicants assertions of utility are legally insufficient or that a person or ordinary skill in the art would reasonably doubt that they could be achieved. As noted above, there is no specific toxicology testing stated, no specific drug to be developed, and no specific disease to be diagnosed. Therefore, Applicants assertions of utility do no meet the legal standards of 35 USC 101 and no person of ordinary skill in the art could guess what toxicology test, drug to be

developed, or disease to be diagnosed would be based on the expression pattern of the claimed polypeptide.

Applicants assert that the Guidelines are themselves inconsistent with the law at pages 8-21. The Examiner will only address parts of this critique as it applies to the instant invention and rejection.

Applicants assert that the use of expression profiling has a well-established utility as tools for toxicology testing, drug discovery, and diagnosis of disease (IA at page 8-11). As noted above, what toxicology testing that the expression pattern will aid in determining, what drug will be developed by knowing this expression pattern, or what disease will be diagnosed by knowing this expression pattern is not provided. Applicants are asking others to use their polypeptide to determine what it is useful for – the toxicology of nicotine? the development of drugs to treat Alzheimer's? the diagnosis of breast cancer? for example. Therefore, this argument is not persuasive.

Applicants assert that the use of IMP-2 proteins for toxicology testing, drug discovery, and diagnosis of disease because practical, beneficial use and not functionality is at the core of the utility requirement (IB1 at page 11-12). Applicants assert that the claimed inventions is known to be useful, for example, in toxicology test to determine whether a drug or toxin changes the expression pattern of the protein, or to determine whether a specific medical condition affects the expression of the protein, or serve as a marker for or to assess the stage of a particular disease or condition. Applicants do not provide any information regarding what drug or toxin will affect the expression pattern of the protein or what it may mean. Applicants do not provide any information as to any medical condition that may affect the expression pattern of the protein or what it may mean. Applicants do not provide any information as to what disease or condition the protein could be a marker for. As noted above, what toxicology testing that the expression pattern will aid in determining, what drug will be developed by knowing this expression pattern, or what disease will be diagnosed by knowing this expression pattern is not provided. Applicants are asking others to use their polypeptide to determine what the polypeptide is useful

for – the toxicology of nicotine? the development of drugs to treat Alzheimer's? the diagnosis of breast cancer? for example. Therefore, this argument is not persuasive.

Applicants assert (IB2 at pages 12-15) that the invention is a member of a broad class of DNA in general which include those sequences having utility. Therefore Applicants conclude that the generally utility for the class is sufficient for the claimed species and that all isolated and purified polynucleotide and polypeptide sequences which are expressable can be and are used in a real-world context as tools for toxicology testing such as for drug discovery purposes. This argument is not persuasive for all of the reasons provided above.

Applicants argue (IC at pages 15-16) that the use of the protein as a research tool is a substantial utility and cite such uses as diagnosis of disease for example. Again, no disease is stated that can be diagnosed by knowing the expression pattern of the IMP-2 protein. Therefore, this argument is not persuasive because one skilled in the art would have to determine for themselves which disease could be diagnosed by knowing the expression pattern of the claimed protein.

Applicants assert (ID at page 16) that the sale of the sequences of the claimed polypeptide to databases is evidence of utility. This argument is noted but this deals with nonfunctional descriptive material, that is, the sequences of bases having no known function. While the arguments deal with the database, the database structure may or may not be patentable, the data in the database is not patentable. Since the data is nonfunctional and descriptive material, the arguments are moot and not on point.

Applicants assert that the Examiner failed to demonstrate that a person of ordinary skill in the art would reasonable doubt the utility of the claimed invention.(II at page17-19). All of these arguments have been addressed above. No specific, substantial, or well-established utility has been provided in the specification or by Applicants. Therefore, there is not utility provided for a person of ordinary skill to doubt.

Applicants again assert that the Guidelines misstate the law (III at pages 19-20). As noted above, the Examiner will not comment on the Guidelines.

Applicants assert that the Examiner failed to demonstrate that a person of ordinary skill in the art would reasonable doubt the utility of the claimed invention.(II at page17-19). All of these arguments have been addressed above. No specific, substantial, or well-established utility has been provided in the specification or by Applicants. Therefore, there is not utility provided for a person of ordinary skill to doubt.

Applicants again assert that the Guidelines misstate the law (III at pages 19-20). As noted above, the Examiner will not comment on the Guidelines.

Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not teach naturally occurring amino acid sequences having at least 90% sequence identity to an amino acid sequence of SEQ ID NO:1. Therefore, one skilled in the art would not know what this naturally occurring sequence would look like, or if the sequence represents a functional protein.

The specification does not teach biologically active fragments of SEQ ID NO:1. As noted above, no biological activity has been attributed to SEQ ID NO:1, and therefore no assay can be used to determine a biological activity of the fragment of SEQ ID NO:1.

The specification does not teach immunological fragments of SEQ ID NO:1. No immunological fragments has been made from SEQ ID NO:1, and therefore it cannot be determined what an immunological fragment of SEQ ID NO:1 is, or how to determine it.

This rejection has not been addressed by Applicants.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 11 are again rejected under 35 U.S.C. 102(a) as being anticipated by Deleersnijder et al. (1996; J. Biol. Chem. 271:19475-19482). As noted by Applicants in Figure 2, Deleersnijder et al. teach a E24AMM protein comprising fragments of SEQ ID NO:1. Therefore, Deleersnijder et al. teach biologically active fragments and immunological fragments of SEQ ID NO:1.

Applicants argue that Deleersnijder et al. do not teach 15 consecutive amino acids in SEQ ID NO:1. The claims do not require 15 consecutive amino acids. Therefore, this argument is not persuasive.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:30 AM - 5:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

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September 20, 2000

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER